

REMARKS

In the Office Action, Claim 21 is rejected under 35 U.S.C. §112 second paragraph; and Claims 1, 3-9, 11-13, 16-19, 23, 25-28 are rejected under 35 U.S.C. §103. Claims 29-31 have been allowed. Applicants believe that the objection and rejection to the claims should be withdrawn for at least the reasons set forth below.

At the outset, Claim 21 is rejected under 35 U.S.C. §112 second paragraph. The Patent Office alleges that Claim 21 is redundant with Claim 30. Applicants believe that this is improper.

Claim 21 as presently pending recites a sterilized liquid beverage which contains polyphenols and a stable iron-fortification system. The iron fortification system includes an iron-protein hydrolysate complex of ferrous irons chelated to partially hydrolyzed egg white protein, wherein the partially hydrolyzed egg white protein has a molecular weight in the range of about 2,000 to about 6,000. Claim 30 recites a sterilized liquid beverage, in part, wherein the sterilized liquid beverage is a tea beverage. Therefore, Claim 21 and Claim 30 should not be considered redundant and thus Applicants respectfully request that the rejection with respect to Claim 21 pursuant to 35 U.S.C. §112 second paragraph be withdrawn, and thus, claim 21 should be rendered allowable as further indicated on page 5 of the Office Action.

With respect to the obviousness rejection, Applicants believe that this rejection is improper as well. At the outset, claim 9 was canceled without prejudice or disclaimer in Applicants' Amendment previously submitted on September 9, 2004, and thus, the obviousness rejection with respect to same should be rendered moot. In further support of Applicants' position, Applicants are submitting herewith the Affidavit of Alexander Sher ("Affidavit") pursuant to 37 C.F.R. §1.132 and as further detailed below.

Of the pending claims at issue, Claims 1, 8, 13, 19, 21, 23 and 25 are the sole independent claims. The claimed invention includes, in part, an iron-protein hydrolysate complex that includes, for example, ferrous iron chelated to a partially hydrolyzed egg white protein that has a molecular weight ranging from about 2,000 to about 6,000.

The supplementation of iron sensitive food products with soluble forms of iron is restricted because of the pro-oxidative properties of iron and its ability to produce dark grayish-black chromogens with polyphenols. When attempted, supplementation, has been either with insoluble salts or encapsulated forms. These ingredients, however, have a disadvantage due to

poor bioavailability. It is also known that iron complexes which are prepared from intact egg white protein or extensively hydrolyzed egg white protein are not sufficiently strong to prevent discoloration of polyphenol containing beverages/food. *See*, Affidavit, paragraph 3.

The present invention is based on the discovery that partially hydrolyzed egg white protein can strongly complex with ferrous ions and further provide the iron in a bioavailable form. This provides a unique iron source that combines both good functionality (e.g., color, flavor, inhibition of lipid oxidation caused by added iron, strong complex) and high bioavailability. *See*, Affidavit, paragraph 4.

Applicants have conducted experiments that demonstrated the desirable properties of functionality and bioavailability with respect to the iron complex as claimed that includes a specific fraction (e.g., about 2000 to about 6000 molecular weight) of polypeptides derived from a specific protein (e.g., egg white). *See*, Applicants' Specification, pages 8-14; and *see also*, Affidavit, paragraph 5.

Even if combinable, the cited art fails to disclose or suggest the claimed invention. For example, the primary Medical Research publication fails to disclose or suggest an iron-protein hydrolysate complex that includes ferrous iron chelated to partially hydrolyzed egg white protein with the molecular weight that ranges from about 2,000 to about 6,000 as claimed. In contrast, the focus of the Medical Research reference relates to iron compounds of amino acids and not proteins. As further detailed in this publication, "[t]o be of any appreciable metabolic value, iron must be in combination with amino acids. . . ." *See*, Medical Research, p. 1, lines 35-41; and *see also*, Affidavit, paragraph 8.

Indeed, the Medical Research publication further provides "the preparation of a complex admixture of amino acids salts of iron. . . by enzymatically digesting a [protein] material to free amino acids therefrom." Moreover, the digestion procedure is carried out to provide a high amino acid yield, thus exhausting the proteins present as far as possible as further detailed in the Medical Research publication. *See* Medical Research, p. 2, lines 18-25. Clearly, one skilled in art would consider the iron compounds of amino acids as provided in the Medical Research publication to be different than an iron-protein complex, let alone an iron-protein hydrolysate complex as claimed and as further supported by the Affidavit at paragraph 9.

In further contrast to the claimed invention, the Medical Research publication also favors the use of casein as the protein substance. Indeed, the Medical Research publication merely

identifies one specific example for preparing the iron compound where this example includes the use of casein. *See*, Medical Research, p. 2, lines 57-81; and *see also* Affidavit at paragraph 10.

In contrast, the iron complex as claimed includes partially hydrolyzed egg white protein that ranges from about 2,000 to about 6,000. Again, Applicants have found that this specific type of protein complex at this specific type of molecular weight range is extremely stable and further can provide iron in bio-available form. Based on at least these reasons, one skilled in the art should consider the Medical Research publication distinguishable from the claimed invention as further supported in the Affidavit at paragraph 11.

Further, Applicants do not believe that the remaining cited references can remedy the deficiencies of the Medical Research reference. With respect to the Barani reference, this reference relates to compounds of bio-available iron with a specific type of an isolated protein where the hydrolysis of such isolated protein is merely optional. *See*, Barani, p. 5, lines 4-6. Indeed, the sole example in Barani describes an iron compound that is made from an intact isolated protein. *See*, Bariani, pgs. 5-7 as further supported in the Affidavit at paragraph 12. Again, the claimed invention is based on the discovery that partially hydrolyzed egg white protein can strongly complex with ferrous iron and further provide the iron in bio-available form.

In Kaishi, the primary emphasis relates to the antioxidant activity of hydrolysates of four different proteins that use eight different proteases. Egg white albumin hydrolyzes according to Amino S displayed the highest antioxidant activity. From this hydrolysate, three specific peptides were isolated and their antioxidant effects were compared. Moreover, iron was merely used in the Kaishi reference as a tool to obtain a measure of the purported antioxidant activity. *See*, Kaishi, abstract and figures and as further supported in the Affidavit at paragraphs 13 and 14. Thus, one who is skilled in the art viewing Kaishi would not be led to prepare a stable complex to fortify food stuffs, let alone one that includes iron as further supported by the Affidavit at paragraph 14.

Further, Applicants believe that this reference effectively teaches away from the claimed invention, particularly with respect to a partially hydrolyzed egg white protein that has a molecular weight that ranges from about 2,000 to about 6,000. Indeed, the most active peptide disclosed in this reference includes three amino acids where the P1 peptide was purported to be twice as active as both another peptide of similar size (P2) and a much larger peptide (P3), and where the largest P3 peptide has a molecular weight of 927. *See*, Affidavit, paragraph 15.

What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejection. Of course, this is improper as a matter of law. Again, the primary Medical Research reference relates to an iron compound of amino acids and not protein and thus on its own effectively teaches away from an iron-protein hydrolysate complex as claimed. The focus of the Barani reference relates to an isolated protein where hydrolysis is merely optional as previously discussed. At a minimum, the Kaishi reference teaches away from the claimed invention where it purports the highest antioxidant activity with respect to a peptide that has a molecular weight well below the lower limit of molecular weight of about 2,000 as claimed.

Nowhere would the cited art lead one skilled in the art to predict that an iron complex with any intermediate ligand(s) (e.g., fractions of polypeptides) would form a much stronger complex than with free amino acids or with an intact protein. Further, nowhere would the cited art lead one skilled in the art to predict that a specific egg white protein used for hydrolysis, let alone that a range of polypeptides derived from this specific egg white protein should range from about 2000 to about 6000 molecular weight, to provide an iron complex that is both strong and highly bioavailable. Again, the claimed invention is based on the discovery that an iron complex with a specific polypeptide fraction (e.g., about 2000 to about 6000 molecular weight) derived from a specific egg white protein provides both desirable functionality and bioavailability that Applicants have demonstrated with experimentation as discussed above. Therefore, Applicants do not believe that one skilled in the art would be inclined to modify the Medical Research reference in view of Barani and Kaishi to cover the claimed invention and as further supported by the Affidavit on paragraph 16.

Based on at least these reasons, Applicants believe that the cited art is distinguishable from the claimed invention. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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